



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,239	12/08/2000	James Blake	02558P-001340US	1694

20350 7590 06/15/2004

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,239

Applicant(s)

BLAKE ET AL.

Examiner

Emily Le

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/16/01 and 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/29/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in Applicant's 04/23/2004 response. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

2. Claims 1-28 are pending in the instant application. Claims 29-47 are cancelled by Applicant's Preliminary Amendment filed 07/16/2001. Claims 14-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Applicant's 04/23/2004 response. Claims 1-13 are currently under examination.

Priority

3. The priority date of the instant application is the filing date of the instant specification, 12/08/2000. Applicant is not granted any of the priority dates that would have been provided by related applications because copendency between the current application and one of the prior applications is absent.

Specification

4. The disclosure is objected to because of the following informalities: All listed sequences, including within the specification and the claims, are not accompanied by a specific sequence identification number, SEQ ID NO:.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to peptide compositions. Currently, as written, the claims read on a product of nature. The claims do not require the claimed peptide be isolated peptide, which implies that the "hand-of-man" was involved. Therefore, because the claims read on a product of nature, the claims are directed to non-statutory subject matter under 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, it is unclear what is intended by the recitation "immunoreactive", which is presented in claims 1 and 8. It is unclear if the term is directed to an induction of an immune response. If it is, then what kind of immune response (cellular or humoral) is being induced and what particular activity is encompassed by the induction?

Secondly, it is unclear what is intended by the term "native protein", which is recited in claim 1. From the recitation, it is unclear what the metes and bounds are by

the term. This is so because the term native is a relative term. A product that is indigenous to a certain population may be extraneous in another population. Specifically, the term is rendered indefinite because the claim(s) do not contain a limitation that would allow identification of the source wherein the protein is considered to be native to the host.

In addition, it is unclear what is intended by the following recitation " reversibly protected by chemically reversible means". From the recitation, it is noted that the thiol groups is reversibly protected chemically, however, it is unclear what it is being protected from. What Applicant has provided is a mode of operation, chemically, however, the claim is rendered indefinite because it is unclear what type of protection is required.

Further, the recitation " at least about" is also rendered indefinite. This is so because it is unclear from the current recitation what the metes and bounds are of such recitation. That is, "one" would be "about" two residues, but not be "at least". Currently, the claim does not recite a clear range.

The foregoing rejections of claim 1 also affect dependent claims 2-13.

Claim 4 recites the limitation "further comprising a cys residue". This is rendered indefinite because it is unclear from the claim if Applicant is intended to include a third cysteine into the sequence or not, because claim 1, which claim 4 depends on all ready recite cysteine residues. Additionally, it is unclear from the instant claim which N-terminus is the cysteine residue attached. Is the cysteine residue attached to the N-terminus of the other cysteine residue, the N-terminus of other amino acid(s) that is

Art Unit: 1648

present in the peptide, or the N-terminus of the peptide--as a whole? In addition, the recitation "which is not protected from oxidation" is indefinite. It is unclear if it is the third cysteine residue is not protected from oxidation, and the N-terminus in which the third cysteine residue is attached is not protected from oxidation.

Concerning claim 5, the claims require that the N-terminal amino acids comprise "cys-gly-gly"; however, it is unclear which N-terminal is intended by the current claim. Is it the N-terminal of all amino acids that is present in the peptide, one of the cys residue, both of the cys residues, all three of the cys residues, or the peptide as a whole? Additionally, it is unclear if the cys that is recited in the fragment, cys-gly-gly, is directed at the first cys residue, second residue, third residue, or is this another cys residue that is added to the claimed invention, making it the fourth cys residue present in the claimed invention.

Claim 6 is also indefinite due to the lack of clarity for which amino acid the recitation "c-terminus" is directed.

Claim 10, the instant claim is also indefinite. First, like the N-terminal/N-terminus analysis made above for claims 4-6, the instant claim is also indefinite due to the lack of clarity for which amino acid the recitation "N-terminus" is directed.

Claim 11, it is unclear if the location of the newly added cys, which is not protected from oxidation, is at the N-terminus of the peptide prior to the addition of other amino acids, including the instant cys; or after the addition of other amino acids--if this is what is intended, then, after which added amino acid.

Claim 12, it is unclear if the cys-gly-gly residue that is recited in the instant claim, includes the cys residue that is newly added and not protected from oxidation. Currently as written, it appears that the N-terminus sequence is a different entity than that of the N-terminus that is recited in claim 10.

8. The following is lack of antecedent basis rejection(s):

Claim 4 recites the limitation "N-terminus" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "N-terminal" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "C-terminus" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "N-terminus" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim. This also affects claim 12.

Claim 11 recites the limitation "N-terminal" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "C-terminus" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1648

10. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Blake et al., see WO 90/15071, published December 13, 1990; and attached sequence alignment. The instant reference constitutes as prior art because the priority date of the instantly claimed invention is 12/08/2000, see Priority section of the instant office action for details.

Due to the indefinite rejections made above, the claims are interpreted as follows: The instantly claimed invention is directed to peptides which have two cysteine residues that are reversibly protected by chemical means, wherein the peptide comprises six to fifty amino acids, and the two cysteine residues are separated from one another by at least about 2 but less than 20 non-cys amino acid residues. The claims further limit the protection activity to oxidation, and the chemical means includes ethylcarbamoyl, acetamidomethyl, 3-nitro-2-pyridinesulfinyl or diphenyl-4-pyridylmethyl. The claims are also directed to include another cys residue, wherein the third cys residue is not protected from oxidation, and located at the N-terminus of the claimed peptide. The claims also specify that the third cys residue be attached to gly-gly, making a cys-gly-gly chain; wherein the cys residue is the N-terminus of the claimed peptide. Additionally, the claims also require that the C-terminus amino acid be amidated. The claims also limits the separation between the original cys residues to about 4 to 6 non-cys residues, the peptide be immunoreactive with antibodies to a retroviral transmembrane protein, wherein the protein is HIV-1 gp41 and the peptide comprises at least seven continuous amino acids within the following sequence: cys-

Art Unit: 1648

gly-gly-arg-ile-leu-ala-val-glu-arg-tyr-leu-lys-asp-gln-gln-leu-leu-gly-ile-trp-gly-cys-ser-gly-lys-leu-ile-cys.

Blake et al. teaches a peptide that comprises of 29 amino acids. This number of amino acids is within the claimed range, six to fifty amino acids. The peptide of Blake et al. comprises two cys residues that are reversibly protected from oxidation by includes ethylcarbamoyl, acetamidomethyl, 3-nitro-2-pyridinesulfinyl or diphenyl-4-pyridylmethyl. The type of reversible protection and chemical means taught by Blake et al. is the same as that instantly claimed. The cys residues of the Blake et al. reference are separated from one another by 5 non-cys amino acid residues. This range of separation is within the ranges that are recited in the claims, at least 2 but less than 20 and about 4 to 6 non-cys amino acid residues. The peptide of Blake et al. also comprises a cys residue that is at the N-terminus of the entire peptide, wherein the third cys residue is not protected from oxidation, and attached to gly-gly, making a cys-gly-gly chain. Additionally, the peptide of Blake et al. comprises an amidated C-terminus. The peptide of Blake et al. is immunoreactive with antibodies to a retroviral transmembrane protein, wherein the protein is HIV-1 gp41 and the peptide comprises at least seven continuous amino acids within the following sequence: cys-gly-gly-arg-ile-leu-ala-val-glu-arg-tyr-leu-lys-asp-gln-gln-leu-leu-gly-ile-trp-gly-cys-ser-gly-lys-leu-ile-cys. Therefore, Blake et al. anticipates the instantly claimed invention.


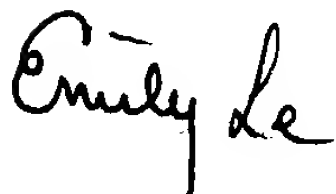
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le



Sharon Foley
Patent Examiner, AU 1648